NDA 75-749 November 21, 2001

International Medication Systems, Limited
Attention: Diane G. Gerst
1886 Santa Anita Avenue
South El Monte, CA 91733

Dear Madam:

This is in reference to your new drug application dated November 30, 1999, submitted pursuant to Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (Act), for Diltiazem Hydrochloride Injection, 5 mg/mL, packaged in 25 mg/5 mL Min-I-Jet® Single-Dose Syringes and 50 mg/10 mL Dilute-A-Jet® Single-Dose Syringes.

Reference is also made to your amendments dated July 20 and August 7, 2000; and January 24, March 1, May 1, May 22, June 13, September 25, October 30, November 14, and November 15, 2001.

We have completed the review of this application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the application is approved. The drug product, Diltiazem Hydrochloride Injection, 5 mg/mL, can be expected to have the same therapeutic effect as that of the listed drug product upon which the Agency relied as the basis of safety and effectiveness.

Under Section 506A of the Act, certain changes in the conditions described in this application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy that you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research